

Remarks/Arguments

I. Status of Claims

Claims 5, 9, 11, 13, 15-16, 18, 20, 25 and 26 are currently pending, with claims 1-4, 17 and 21 withdrawn from consideration as drawn to a non-elected invention. Claims 6-8, 10, 12, 14, 19, and 22-24 have previously been canceled. Claims 5, 9, 11, 13 and 15 are amended upon entry of this amendment. These amendments are supported throughout the specification including, for example, page 4, lines 20-31.

II. Rejection under 35 U.S.C. §112, first paragraph

Claims 5, 9, 11, 13 and 15 stand rejected because they allegedly are directed to subject matter that is not described in the specification in such a way as to reasonably convey, at the time the application was filed, that the inventors had possession of the claimed subject matter. For the reasons that follow, Applicants respectfully disagree.

Claims 5 and 13 are rejected because parts (b) and (c) of these claims are said to define soluble RANK with respect to broad hybridization language or in broad percent identity language. With respect to this issue, the Written Description Guidelines provide that a claim directed to a genus (e.g., independent claims 5 and 13) can satisfy the written description requirement by, for example, disclosing "relevant identifying characteristics" (Fed. Reg., vol. 66, page 1099 (January 5, 2001)). Examples of such characteristics are said to include: (1) structures or other chemical or physical properties, (2) functional characteristics coupled with a known or disclosed correlation between structure and function, or (3) combinations of such identifying characteristics.

The specification and claims satisfy the written description requirement by disclosing several relevant identifying characteristics. For example, part (b) of claims 5 and 13 as currently amended define certain RANK polypeptides as those that are encoded by a DNA that is capable of hybridizing to a DNA consisting of the nucleotide sequence of SEQ ID NO:1 under specifically defined conditions. Part (c) of claims 5 and 13 as currently amended recite to certain soluble RANK polypeptides that have greater than 90% sequence identity to certain defined regions of SEQ ID NO:2. Both of these sections thus satisfy the structural criterion set forth in (1).

The claims and specification further satisfy the criterion of (2) by defining the soluble RANK polypeptides of sections (b) and (c) in functional terms coupled with a disclosed relationship between structure and function. The specification and current

claims, for example, state that a soluble RANK polypeptide as presently claimed "is capable of binding to a RANKL polypeptide that consists of amino acids 1-317 of SEQ ID NO:8" (a functional characteristic). Part (b) of current claims 5 and 13 and the specification also states that certain soluble RANK polypeptides with such activity are ones with an amino acid sequence that is encoded by a DNA that hybridizes to a DNA consisting of the nucleotide sequence of SEQ ID NO:1 under specifically defined conditions (a structural characteristic). See, e.g., page 2, lines 13-14 and page 4, lines 20-26. With respect to part (c) of claims 5 and 13, the specification and these claim sections state that some soluble RANK polypeptides with RANKL binding activity are ones that have greater than 90% sequence identity to the specified regions of SEQ ID NO:2 (another structural characteristic). See, e.g., page 2, lines 13-14 and page 4, lines 30-31. Thus, the claims and the specification also define soluble RANK polypeptides in terms of function and a corresponding structure, thereby satisfying criterion (2).

Furthermore, section (c) of claims 5 and 13 as currently amended are in accord with the type of claim discussed in Example 14 of the "Synopsis of Application of Written Description Guidelines" (Synopsis), a claim which the Patent Office says satisfies the written description requirements. Example 14 is directly analogous to the section (c) of claims 5 and 13. The claim in Example 14 reads as follows:

A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B.

Because the claim defines the genus in functional terms that are related to a disclosed correlation between structure and function (see Written Description Guidelines criteria above), the Synopsis concludes that the disclosure meets the written description requirements with respect to this exemplary claim. Part (c) of independent claims 5 and 13 as presently amended is in the same format as this claim (i.e., linking functional characteristics to structural characteristics). As noted above, this relationship is fully supported by the specification. So by analogy, part (c) of currently amended claims 5 and 13 satisfy the written description requirements for the same reasons as the exemplary claim presented in Example 14 of the Synopsis.

Thus, for all the foregoing reasons, the specification and currently amended claims satisfy the written description requirements as set forth in the Written Description Guidelines.

III. Rejection under 35 U.S.C. §112, second paragraph

The pending claims are rejected as allegedly being indefinite for failing to adequately disclose the nature of the hybridization conditions and for omitting an essential element, namely the washing conditions during hybridization. In response, claims 5 and 13 have been amended to more explicitly describe the hybridization and washing conditions. These amendments simply make explicit what was previously implicit, and thus do not narrow the claims.

IV. Declaration

A new declaration is enclosed, which is consistent with the amendment to the priority section made in the previous response.

V. Abstract

A new abstract is submitted with this response to bring the abstract into closer conformity with the subject matter that is currently claimed in this application.

VI. Information Disclosure Statement

A supplemental information disclosure statement was submitted on November 15, 2004. It does not appear from Applicant's records, however, that a signed copy of the IDS has been received showing consideration by the Examiner. Although it appears from PAIR that this IDS and the references cited in that IDS are available to the Examiner, another copy of the IDS and copies of the non-patent documents are enclosed with this paper for the convenience of the Examiner. Applicants request that the Examiner consider the documents listed in this IDS and provide a signed copy of the IDS with the next communication.

VI. Attorney Docket No.

Please change the Office's records to reflect the change in Attorney Docket No. to 2874-US-CNT.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-265-7858.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Scott Ausenhus", written over a horizontal line.

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